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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,315	04/14/2005	Gilles Pauly	C 2534 PCT/US	8331
23657	7590	01/28/2010		
FOX ROTHSCHILD LLP 997 Lenox Drive, Bldg. #3 Lawrenceville, NJ 08648				
EXAMINER				
WELTER, RACHAEL E				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
01/28/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary

Application No.

10/506,315

Applicant(s)

PAULY ET AL.

Examiner

RACHAEL E. WELTER

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-22 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claim Status

Claims 17-30 are pending. Claims 1-16 are cancelled. Claims 17-22 and 25-30 are drawn to the elected species. Claims 23-24 are withdrawn.

Acknowledgements

Receipt of the claim/specification amendments and remarks/arguments filed on 11/13/09 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 17-19, 21, and 25-26 rejected under 35 U.S.C. 102(b) as being anticipated by Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025) is maintained.

Handa et al teach a pharmaceutical composition for the external treatment of skin wounds comprising 2-40 wt.% of the total weight of the composition of a mono- or disaccharide fatty acid ester and a prophylactically effective amount of an anti-infective agent (column 2, lines 31-43). According to Handa et al, the sugar moiety of said sugar fatty acid ester can be fructose, sucrose, lactose, and sugar alcohols (column 2, lines 44-47) and the fatty acid moiety is a fatty acid saturated or unsaturated fatty acid

containing 6-22 carbon atoms (claim 3), such as palmitic acid, lauric acid, oleic acid, etc (column 2, lines 47-52). In example 5, Handa et al teach an ointment comprising sucrose fatty acid ester (DK Ester F-160) (column 6, lines 21-22). As evidenced by Jaspers et al, according to Table 2 (corrected percentage), DK F-160 has an average degree of esterification from approximately 1.23-1.46 (pg. 1022).

Regarding the limitations directed to the inhibition of melanin synthesis in skin and/or hair in claim 17, the examiner contends that since Handa et al teach a composition applied to human's skin comprising a sugar ester in an effective amount, it is implicit that the ability of skin or hair to synthesize melanin would be inhibited as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The rejection of claims 20, 22, 27-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025) is maintained.

The disclosure of Handa et al is discussed above. The examiner notes that Handa et al suggest sugar moieties such as fructose and fatty acid moieties having from 8-16 carbon atoms, which include caprylic acid, lauric acid, myristic acid, and palmitic acid.

Although Handa et al suggest the use of both fructose as a sugar moiety and fatty acid moieties with 8-16 carbon atoms, it is not immediately envisaged and therefore the instant rejection is made under obviousness.

However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Handa et al and incorporate such moieties in the pharmaceutical composition. One would have been motivated to do so since Handa et al suggest the use of fructose palmitate, fructose myristate, etc as suitable alternatives among sugar fatty acid esters. Furthermore, it is within the skill of an artisan to select a given sugar fatty acid ester depending on costs, availability, and its degree in treating skin wounds such as a pressure sore.

Regarding claims 27-29, wherein the amount of sugar ester is present from 0.0001-10 wt.% and more specifically 0.01-1 wt.% based on the composition, the examiner notes that Handa et al teach an amount from 2-40 wt.%. Therefore, it would

have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the sugar fatty acid ester taught in the pharmaceutical composition of Handa et al. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results of effectively treating skin wounds. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05. The examiner notes that applicant can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range.

Regarding claim 30, wherein the composition comprises a plurality of sugar esters, the examiner notes that Handa et al do not explicitly teach a composition comprising more than one sugar ester. However, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add more than one sugar ester to the composition of Handa et al. One would have been motivated to do so in order to possibly enhance the effect of treating skin tissue surrounding a pressure sore. Furthermore, the examiner notes that one would expect that a composition comprising two or more sugar esters would result in a complementary or possibly synergistic effect. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from

their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

Regarding the limitations directed to the inhibition of melanin synthesis in skin and/or hair in claim 30, the examiner contends that since Handa et al suggest a composition applied to human's skin comprising a plurality of sugar esters in an effective amount, it is implicit that the ability of skin or hair to synthesize melanin would be inhibited as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Response to Arguments

Applicant's arguments filed 11/13/09 have been fully considered but they are not persuasive.

Applicant argues that Handa does not disclose or suggest a method of inhibiting the synthesis of melanin in skin or hair by applying a composition comprising a sugar ester in an amount effective to inhibit the synthesis of melanin. Applicant notes that Handa is directed to the treatment of skin wounds, such as pressure sores. As such, applicant argues that the presently amended claims are novel and unobvious over Handa.

In response to applicant's arguments, the examiner contends that since Handa teaches a composition applied to human's skin comprising a sugar ester in an effective amount, it is implicit that the ability of skin or hair to synthesize melanin would be

inhibited as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). The examiner notes that the patient population to whom the composition is being administered is not defined in independent claims 17 and 30. As such, it is the position of the examiner that the instant claims are still anticipated/rendered obvious over Handa and that one would expect the inhibition of melanin synthesis in the skin.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17-18 and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10, and 12-

13 of copending Application No. 12/294,203. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending claims are drawn to a skin whitening composition comprising a sugar fatty acid ester, wherein the fatty acid moiety RCO is a linear or branched, saturated or unsaturated acyl or hydroxyacyl group having from 6-22 carbon atoms. The sugar is selected from the group consisting of monosaccharides, disaccharides, and mixtures thereof. The sugar ester along with a plant extract can be present in a concentration from 0.1-10 wt.% of the composition. The copending claims further claim a method of applying the composition to the skin and a method of inhibiting melanogenesis.

Thus, the copending claims anticipate the method of instant claims 17-18 and 21.

Furthermore, because the instant claims recite "a composition comprising...", the claims are inclusive or open-ended and do not exclude additional, unrecited elements or method steps, such as a plant extract and an additional skin whitening agent. See MPEP 2111.03.

Claims 19-20, 22, and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 12/294,203 in view of Handa et al (EP 0343671) as evidenced by Jaspers et al (JAOCS, Vol. 64, no. 7, July 1987, pp. 1020-1025). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Although the copending claims are drawn to a sugar fatty acid ester, the copending claims are not explicitly drawn to a sugar selected from fructose, glucose, trehalose, sucrose, and mixtures thereof.

Handa et al teach a pharmaceutical composition for the external treatment of skin comprising 2-40 wt.% of the total weight of the composition of a mono- or disaccharide fatty acid ester and a prophylactically effective amount of an antiinfective agent (column 2, lines 31-43). According to Handa et al, the sugar moiety of said sugar fatty acid ester can be fructose, sucrose, lactose, and sugar alcohols (column 2, lines 44-47) and the fatty acid moiety is a fatty acid saturated or unsaturated fatty acid containing 6-22 carbon atoms (claim 3), such as palmitic acid, lauric acid, oleic acid, etc (column 2, lines 47-52). In example 5, Handa et al teach an ointment comprising sucrose fatty acid ester (DK Ester F-160) (column 6, lines 21-22). As evidenced by Jaspers et al, according to Table 2 (corrected percentage), DK F-160 has an average degree of esterification from approximately 1.23-1.46 (pg. 1022). Handa et al further suggest sugar moieties such as fructose and fatty acid moieties having from 8-16 carbon atoms, which include caprylic acid, lauric acid, myristic acid, and palmitic acid.

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to use sugars, such as fructose, sucrose, and lactose as taught in Handa et al. One would have been motivated to do so since Handa et al teach that such sugar fatty acid esters are safe and can be used to treat the skin. Furthermore, Handa et al teach that sucrose fatty acid ester is preferred, more specifically DK F-160 with an average esterification degree of approximately 1.23-1.46, because it is

commonly used in food and drug products available from commercial sources (column 2, lines 52-55--column 3, lines 1-2; example 5).

Regarding instant claims 27-29, wherein the amount of sugar ester is present from 0.0001-10 wt.% and more specifically 0.01-1 wt.% based on the composition, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the sugar fatty acid ester in the copending claims. Optimization of parameters is a routine practice that would be obvious to a person of ordinary skill in the art to employ and reasonably expect success. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) & MPEP 2144.05.

Regarding instant claim 30, wherein the composition comprises a plurality of sugar esters, it would have been obvious to an artisan of ordinary skill at the time the invention was made to add more than one sugar ester to the composition of the copending claims. One would have been motivated to do so in order to possibly enhance the skin whitening effect of the composition in the copending claims. The examiner notes that one would expect that a composition comprising two or more sugar esters would result in a complementary or possibly synergistic effect. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (see MPEP 2144.06).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant notes they will consider filing a terminal disclaimer for the double patenting rejection above, if the instant claims are otherwise found to be allowable.

Since the instant claims still remain rejected over Handa, the double patenting rejection is maintained for the reasons stated above.

Conclusion

Claims 17-22 and 25-30 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW
/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
January 21, 2010